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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,768	09/22/2003	D. Russell Pflueger	D-3026CON	1359

7590 03/28/2007
Frank J. Uxa
Stout, Uxa, Buyan & Mullins, LLP
Suite 300
4 Venture
Irvine, CA 92618

EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/667,768	Applicant(s) PFLUEGER, D. RUSSELL	
	Examiner Brian Szmaj	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 30-33 and 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dekel (5,591,187) in view of Sirimanne et al (6,136,014).

Dekel discloses a tissue retrieval method and further discloses placing into the tissue of a human or animal, a cannula having an open distal tip and a rotational element disposed at least partially in the cannula; rotating the rotational element relative to the cannula, thereby at least assisting in drawing a material from the breast into the open distal tip of the cannula; passing the material from the tissue through the cannula; percutaneously introducing the cannula into the body, and positioning the open distal tip of the cannula in close proximity to the material to be removed; the material is removed without applying additional suction or aspiration to the open distal tip; the step of rotating is effective to draw material from the surrounding tissue into the open distal tip as a substantially continuous piece; collecting the removed material and/or observing the collected material; the rotational element includes a distal portion that extends beyond the open distal tip of the cannula; the rotational element includes a shaft portion that extends beyond the open distal tip of the cannula; the rotational element includes a distal portion that extends a distance in the range of about 0.02-1.0 inch beyond the open distal tip of the cannula; the open distal tip is beveled; and a collection chamber in

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communication with the cannula and the step of rotating is effective to pass material through the cannula to the collection chamber. See Column 2, lines 20-23; Column 4, lines 21-35 and 46-47; Column 26-30; Column 6, lines 40-46; and Figure 3.

Dekel, as discussed above, discloses the removal of tumors from surrounding tissue, but fail to explicitly disclose the tissue is breast tissue.

Sirimanne et al disclose a percutaneous tissue removal device and further disclose the tissue from which the tumor resides is breast tissue. See Column 3, lines 59-61.

Since both Dekel and Sirimanne et al disclose means for removing tissue from a body, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Dekel to remove tissue from a breast, as per the teachings of Sirimanne et al, since it is well known in the art to remove tissue from the breast for a biopsy.

3. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dekel (5,591,187) and Sirimanne et al (6,136,014) as applied to claim 30 above, and further in view of Shiber (4,883,458).

Dekel and Sirimanne et al, as discussed above, disclose a means for removing tissue from a breast, but fail to disclose the cannula has an outer diameter of no larger than about 5.0 mm; and the cannula has an outer diameter no larger than about 2.0 mm.

Shiber discloses a means for removing tissue and further discloses the cannula has an outer diameter of no larger than about 5.0 mm; and the cannula has an outer diameter no larger than about 2.0 mm. See Column 7, lines 11-15.

Since Dekel, Sirimanne et al and Shiber disclose means for removing tissue from a body, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Dekel and Sirimanne et al to have a cannula with an outer diameter of no larger than 5.0 mm or 2.0mm, as per the teachings of Shiber, since it would provide a means of minimally invasive tissue removal.

4. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dekel (5,591,187) and Sirimanne et al (6,136,014) as applied to claim 44 above, and further in view of Fox (6,325,806 B1).

Dekel and Sirimanne et al, as discussed above, disclose a means for removing tissue from a breast, but fail to disclose the collection chamber is structured to facilitate at least one of quantifying the removed material from the breast and observing the removed materials from the breast.

Fox discloses a material collection system and further discloses the collection chamber is structured to facilitate at least one of quantifying the removed material from the breast and observing the removed materials from the breast. See Column 11, lines 51-56.

Since Dekel, Sirimanne et al and Fox disclose means for removing tissue from a body, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Dekel and Sirimanne et al to include

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the use of a collection chamber that is structured to either quantify the removed material or observe the removed material, as per the teachings of Fox, since it would provide a means of determining the volume of the removed tissue.

Response to Arguments

5. Applicant's arguments filed January 25, 2007 have been fully considered but they are not persuasive. The Applicants argue that Dekel discloses only an instrument for laparoscopic tissue removal within the abdominal cavity. In Column 2, lines 20-23, Dekel clearly discloses the device can be used to remove tissue "elsewhere in a human or animal body" other than the peritoneal cavity. This can be interpreted to broadly encompass the removal of tissue from the breast. Therefore, Dekel discloses placing a cannula with an open distal end into tissue, and rotating the rotational element relative to the cannula to assist in drawing tissue into the cannula. Sirimanne et al shows that a device similar in structure removing tissue from the breast, therefore supporting the disclosure in Dekel using the device "elsewhere in a human or animal body".

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Dekel discloses

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a means for removing tissue "elsewhere in a human or animal body". Sirimanne et al disclose a device similar in structure while disclosing the device removes tissue from the breast.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Dekel, Sirimanne et al and Shiber all disclose means for removing matter from the human body utilizing an auger-type device. Shiber provides the teaching that an auger-type device can have a cannula of no larger than 5.0 or 2.0 mm.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Dekel, Sirimanne et al and Fox all disclose means for removing matter from the human body. Fox

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discloses a collection chamber that one of ordinary skill in the art would be able to use for other types of tissue collection, other than bone marrow collection.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

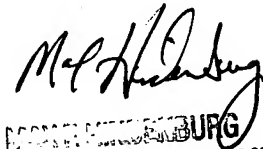
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BS



MICHAEL H. HURLING
PATENT EXAMINER
EBC CENTER STC